Remarks

In the Specification

The specification has been amended to comply with U.S. formatting requirements and to correct certain typographical errors. No new matter has been added. A marked-up copy of the Substitute Specification showing the changes made is enclosed herewith.

Rejection Pursuant to 35 U.S.C. §112, Second Paragraph

In the Office Action, claims 19-40 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite "for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In support of the instant rejection, the Examiner asserted with respect to claim 19 that the relationships of the two ends (of the dosage capillary) are clear for the second position (one end of the capillary being in communication with the diluent chamber and the other end being in communication with the measuring chamber), however, the first position is described as the dosage capillary only being in communication with a sample-loading zone, and that it is not clear what the other end of the capillary is connected to when in the first position.

"Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art the scope of the invention, Section 112 demands no more." *Personalized Media v. Int'l Trade Comm'n,* 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir. 1998). Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *See, e.g., Atmel Corp. v. Information Storage Devices, Inc.,* 198 F.3d 1374, 53 USPQ 2d 1225

(Fed. Cir. 1999), "it is well established that the determination whether a claim is invalid as indefinite 'depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification'" (quoting *North Am. Vaccine Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993)). Moreover, subject matter set forth in the claim must, in the absence of evidence to the contrary, be presumed to be that "which the applicant regards as his invention." *In re Miller*, 441 F.2d 689, 692, 169 USPQ 597 (CCPA 1971); *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236 (CCPA 1971). The "regards" language of Section 112 may be relied upon to reject a claim only "where some material submitted by applicant, *other than his specification,* shows that a claim does not correspond in scope with what *he regards* as his invention." *In re Conley,* 490 F.2d 972, 976, 180 USPQ 454 (CCPA 1974).

Claim 19 recites a single use disposable unit for the analysis of biological liquids comprising, *inter alia*, a sample dosage device comprising a dosage element into which a dosage capillary (13) running between two openings (14, 15) is integrated. The dosage element is arranged inside a dosage element chamber (12) formed in the disposable unit and the dosage element is moveable in such a manner that one opening of the dosage capillary (13) is connected to a sample loading zone (17) of the disposable unit when the dosage element is in a first position. In accordance with the present invention, the other opening of the dosage capillary (13) is arranged inside the dosage element chamber (12). This is clear in light of the language of the claim (see above) as well as the content of the present application. In particular, it is noted at paragraph [0023] of the Substitute Specification that:

> Components of the disposable unit 2 can include a diluent chamber 5, a sample dosage device 6, and a measuring chamber 7. The sample dosage device 6 has a sample dosage element 8, which in the embodiment shown is formed as a rotor element 9 and is arranged and adapted to be rotated around an axis 10 inside a dosage element chamber 12 formed by a rotor housing 11. A dosage capillary 13 with two openings 14 and 15 is integrated into the rotor element 9. The rotor element 9 can be adjusted between (at least) two positions, which differ

> with respect to the orientation of the dosage capillary 13. In the first position one opening 14 of the dosage capillary 13 is connected to the sample loading zone 17 in such a manner that a blood sample present therein flows, driven by capillary forces, into the dosage capillary 13 and fills it completely. The position of the dosage capillary 13 in this first position of the rotor element 9, which is hereafter called the "filling position", is shown with dashed lines in Figure 1.

In the absence of evidence to the contrary, the subject matter set forth in the claim must be presumed to be that "which the applicant regards as his invention." Reading the claim in light of the specification, it is clear that in the first position (the "filling position") one opening of the dosage capillary (13) is connected to the sample loading zone (17). The second opening of the dosage capillary (13) does not necessarily have to be connected to anything in this first position. In the embodiment recited in claim 19, the dosage capillary (13) and, consequently, the second opening is arranged inside the dosage element chamber (12). Claim 19, read in light of the specification reasonably apprises one skilled in the art the scope of the present invention. As noted above, Section 112 of the statute demands no more. Accordingly, in light of the remarks made herein, applicants submit that claim 19 is in compliance with the statute and respectfully request that the rejection be withdrawn.

Rejections Pursuant to 35 U.S.C. §102(b)

Also in the Office Action, claims 19-40 were rejected under 35 U.S.C. §102(b) as being anticipated by Warden et al. (U.S. 6,016,712). In support of the rejection, the Examiner asserted that "[t]he claimed sample-dosing device has been read on the taught manifold, diluent chamber has been read on the first chamber (130) and the measuring chambers on the chambers (160 a-d).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Moreover, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." MPEP 2131 (citing

Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Warden et al. cannot be relied upon in support of the instant rejection. As noted herein, the embodiment of the present invention recited in claim 19 is directed to a single use disposable unit for the analysis of biological liquids, comprising, *inter alia,* a dosage element into which a dosage capillary (13) running between two openings (14, 15) is integrated. The dosage element is moveable in such a manner that one opening of the dosage capillary (13) is connected to a sample loading zone (17) of the disposable unit when the dosage is in a first position, and that, when it is in a second position, one of the openings of the dosage capillary (13) is connected to the diluent chamber (5) and the other opening of the dosage capillary (13) is connected to the measuring chamber (7), so that the diluent chamber (5) and the measuring chamber (7) are in the second position connected to one another via the dosage capillary (13). The position of the dosage capillary (13) in the first position of the rotor element (9) is shown in dashed lines in Fig. 1, and the arrow located in the two o'clock position of the rotor element (9) illustrates the movement of the dosage element between the first and second positions.

In contrast, Warden et al. teach a sample receiving element (120) which comprises a well (122), an input needle (124), and a base (128) **affixed** to the bottom inside wall of the well (122). *See* Fig. 1 and col. 13, lines 50-62 of the '712 patent. The manifold (150) is basically a fixed tube providing fluid communication between a first chamber (130) and second chambers (160a-d). Warden et al. do not teach or suggest a dosage element that is moveable between a first position and a second position and, therefore, cannot anticipate the invention recited in independent claim 19. Claims 20-40 contain all of the limitations of the base claim from which they depend. Accordingly, applicants respectfully request that the rejection be withdrawn.

Conclusion

Applicants have filed a complete response to the outstanding Office Action and respectfully submit that, in view of the above amendments and remarks, the application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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